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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.”

*Office Action*, page 2. However, Applicants respectfully note that because claims 16 and 19 through 23 are cancelled herein, the rejection is moot as it applies to such claims and should be withdrawn. Applicants further submit that the subject matter recited in each of claims 12 through 15, 17, 18, and 24 is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Therefore, Applicants request the rejection of claims 12 through 15, 17, 18, and 24 under Section 112, first paragraph, be withdrawn.

Claims 12-24 also stand rejected under Section 112, second paragraph. However, Applicants again note that claims 16 and 19 through 23 are cancelled herein, and Applicants respectfully submit that the rejection of claims 16 and 19 through 23 under Section 112, second paragraph, is moot and should be withdrawn. Regarding the remaining claims, it is generally asserted in the Office Action that the claims are indefinite. However, Applicants respectfully submit that claims 12 through 15, 17, 18 and 24 particularly point out and distinctly claim subject matter that the applicants regard as the invention. Therefore, Applicants respectfully request that the rejection of the claims 12 through 15, 17, 18 and 24 under Section 112, second paragraph, be withdrawn.

Claims 13 and 19 also stand rejected as being indefinite. In particular, regarding these claims it is asserted that “it is unclear whether the expandable layer must comprise all of the three components (hydrogel, solute and hydroxyalkylcellulose).” *Office Action*, page 3. Applicants note that claim 19 has been cancelled herein and that the rejection of this claim as indefinite is moot and should be withdrawn. Applicants further submit that claim 13 has been amended to read that “the expandable layer comprises an osmotic hydrogel, an osmotically effective solute, and a hydroxyalkylcellulose.” Applicants respectfully request that the rejection of claims 13 and 19 as indefinite be withdrawn.

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**Rejections Under 35 U.S.C. § 102**

Claims 12 through 23 stand rejected under 35 U.S.C. § 102(b) (hereinafter "Section 102(b)") as being anticipated by Wong et al. (U.S. Patent 5,324,280). Because claims 16 and 19 through 23 are cancelled herein, Applicants respectfully submit that the rejection of these claims under Section 102(b) is moot and should be withdrawn. Therefore, Applicants address the rejection under Section 102(b) in light of Wong et al. only as it applies to claims 12 through 15, 17, and 18.

In order for a reference to anticipate a claim under Section 102(b) that references must expressly or inherently set forth each and every element recited in the claim. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that Wong et al. fails to expressly or inherently teach each and every limitation recited in the claims 12 through 15, 17, and 18. In particular, Wong et al. fails to expressly or inherently teach a dosage form comprising a self-emulsifying drug formulation comprising a progestogenic steroid. Therefore, Applicants respectfully submit that the teachings of Wong et al. do not anticipate claims 12 through 15, 17, and 18, and Applicants respectfully request that the rejection of claims 12 through 15, 17, and 18 under Section 102(b) be withdrawn.

Claims 12, 16 through 18, 22 and 23 stand rejected under 35 U.S.C. § 102(e) (hereinafter "Section 102(e)") as being anticipated by Lambert et al. (U.S. Patent 6,458,373 B1). Because claims 16, 22 and 23 are cancelled herein, Applicants respectfully submit that the rejection of these claims under Section 102(e) is moot and should be withdrawn. Therefore, Applicants address the rejection under Section 102(e) in light of Lambert et al. only as it applies to claims 12, 17, and 18.

In order for a reference to anticipate a claim under Section 102(b) that references must expressly or inherently set forth each and every element recited in the claim. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that Lambert et al. fails to expressly or inherently teach each and every limitation recited in the claims 12, 17, and 18. In particular, Lambert et al. fails to expressly or inherently teach a

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sustained release dosage form. The dosage forms discussed in Lambert et al. are simple capsules that break down after administration to provide a bolus dose. Moreover, Lambert et al. does not teach a dosage form that includes a self-emulsifying drug formulation comprising a progestogenic steroid. Therefore, Applicants respectfully submit that the teachings of Lambert et al. do not anticipate claims 12, 17, and 18, and Applicants respectfully request that the rejection of claims 12, 17, and 18 under Section 102(e) be withdrawn.

**35 U.S.C. § 103(a) Obviousness Rejections**

Claims 13 through 15, 19 through 21 and 24 are rejected under 35 U.S.C. § 103(a) ("Section 103") as being unpatentable over Lambert et al. in view of Wong et al. Applicants note that claims 19-21 are canceled herein and respectfully submit that the rejection of these claims under Section 103 is moot and should be withdrawn. Applicants, therefore, address the rejection under Section 103 in light of the combination of Lambert et al. and Wong et al. only as it applies to claims 13 through 15 and 24.

A rejection under Section 103(a) is improper and will be overturned unless a *prima facie* case of obviousness is established against the rejected claims. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). Applicants respectfully submit that the combined teachings of the references cited in the Office Action do not establish the *prima facie* obviousness of any of claims 13 through 15 and 24, and Applicants respectfully request that the rejection of claims 13 through 15 and 24 under Section 103 be withdrawn.

As is set forth in M.P.E.P. 706.02(j), a *prima facie* case of obviousness under Section 103 cannot be established unless three criteria are met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

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It is the examiner that bears the burden of establishing these three criteria through the application of objective teachings or knowledge. *See, M.P.E.P.* § 2142.

In the instant application, Applicants respectfully submit that the combined teachings of Lambert et al. and Wong et al. fail to teach or suggest each of the limitations recited in any of the rejected claims. Moreover, Applicants respectfully submit that the combined teachings of Lambert et al. and Wong et al. would not motivate one of skill in the art to modify the teachings found therein to arrive at the subject matter recited in claims 13 through 15 and 24. Therefore, Applicants respectfully submit that the combined teachings of Lambert et al. and Wong et al. do not establish the *prima facie* obviousness of claims 13 through 15 and 24.

First, Applicants respectfully submit that the combined teachings of Lambert et al. and Wong et al. do not teach or suggest a sustained-release dosage form for the delivery of a progestogenic steroid having all the limitations of any of claims 13 through 15 and 24. Wong et al. teaches sustained release dosage forms, but does not teach or suggest a dosage form having a self-emulsifying formulation comprising a progestogenic steroid. Moreover, Wong et al. does not teach or suggest the potential benefits of fabricating a sustained release dosage form that includes a self-emulsifying formulation. The teachings of Lambert et al. describe emulsions and self-emulsifying formulations. However, Applicants respectfully submit that Lambert et al. does not teach or suggest a self-emulsifying formulation containing a progestogenic steroid, and Lambert et al. further fails to teach a dosage form suitable for sustained release of a self-emulsifying formulation. The bulk of the teachings found in Lambert et al. are directed to emulsion or micellar formulations, and the teachings of Lambert et al. do not suggest the potential benefits of creating a sustained sustained-release dosage form that includes a self-emulsifying drug formulation comprising a progestogenic steroid. Thus, Applicants respectfully submit that the combined teachings of Lambert et al. and Wong et al. do not teach or suggest each of the limitations recited in claims 13 through 15 and 24, and Applicants respectfully request that the rejection of claims 13 through 15 and 24 under Section 103 be withdrawn.

Further, Applicants respectfully submit that the combined teachings of Lambert et al. and Wong et al. would not motivate one of ordinary skill in the art to modify the teachings of the

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references to arrive at the subject matter recited in claims 13 through 15 and 24. Specifically, Wong et al. includes no teaching or suggestion regarding self-emulsifying formulations, and Applicants respectfully submit that the teachings of Lambert et al. make no recognition of the benefits to be achieved by creating a sustained release dosage form for the delivery of a self-emulsifying formulation. In fact, the dosage forms taught in Lambert et al. are simply capsules capable of delivering a bolus dose. Applicants respectfully submit that, from the combined teachings of Lambert et al. and Wong et al., one of skill in the art would not appreciate the benefits to be achieved by dosage forms having all the limitations recited in any of claims 13 through 15 and 24. Therefore, Applicants respectfully submit that the combination of Lambert et al. and Wong et al. would not motivate one of skill in the art arrive at the subject matter recited in any of claims 13 through 15 and 24, and Applicants respectfully request that the rejection of claims 13 through 15 and 24 under Section 103 be withdrawn.

**CONCLUSION**

Claims 12 through 15, 17, 18 and 24 are believed to be in condition for allowance, and a notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, she is respectfully invited to contact Applicants' undersigned attorney.

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Respectfully Submitted,



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